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Techniques and materials for skin closure in caesarean section (Review)

Mackeen AD, Berghella V, Larsen ML

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TABLE OF CONTENTS

[Intervention Review]

Techniques and materials for skin closure in caesarean section

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ABSTRACT

Background

Caesarean section is a common operation with no agreed upon standard regarding certain operative techniques or materials to use. With regard to skin closure, the skin incision can be re-approximated by a subcuticular suture immediately below the skin layer, by an interrupted suture, or by staples. A great variety of materials and techniques are used for skin closure after caesarean section and there is a need to identify which provide the best outcomes for women.

Objectives

To compare the effects of skin closure techniques and materials on maternal and operative outcomes after caesarean section.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (10 January 2012).

Selection criteria

All randomized trials comparing different skin closure materials in caesareans were selected. Two review authors independently abstracted the data.

Data collection and analysis

We identified 19 trials and included 11, but only eight trials contributed data. Three trials were not randomized controlled trials; two were ongoing; one study was terminated and the results were not available for review; one is awaiting classification; and one did not compare skin closure materials, but rather suture to suture and drain placement.

Main results

The two methods of skin closure for caesarean that have been most often compared are non-absorbable staples and absorbable subcutaneous sutures. Compared with absorbable subcutaneous sutures, non-absorbable staples are associated with similar incidences of wound infection. Other important secondary outcomes, such as wound complications, were also similar between the groups in women with Pfannenstiel incisions. However, it is important to note, that for both of these outcomes (wound infection and wound complication), staples may have a differential effect depending on the type of skin incision, i.e., Pfannenstiel or vertical. Compared with absorbable subcutaneous sutures, non-absorbable staples are associated with an increased risk of skin separation, and therefore, reclosure. However, skin separation was variably defined across trials, and most staples were removed before four days postpartum.

Authors' conclusions

There is currently no conclusive evidence about how the skin should be closed after caesarean section. Staples are associated with similar outcomes in terms of wound infection, pain and cosmesis compared with sutures, and these two are the most commonly studied methods for skin closure after caesarean section. If staples are removed on day three, there is an increased incidence of skin separation and the need for reclosure compared with absorbable sutures.

PLAIN LANGUAGE SUMMARY

Techniques and materials for skin closure in caesarean

When performing a caesarean, several layers of the mother's abdomen need to be cut to reach the baby. After the baby's birth, the layers need to be closed again. This review looked at different ways of closing the skin layer after a caesarean. Skin closure can be carried out with stitches that go under the skin, stitches that go over the skin or staples (clips). Suture materials currently available are natural or synthetic, absorbable or non-absorbable, single-filament or braided. Staples are attractive because of the speed of application.

We identified 19 randomized controlled trials and included 11, but only eight contributed data. The most commonly studied methods of skin closure were non-absorbable staples compared with absorbable subcutaneous sutures. Staples were associated with similar outcomes in terms of wound infection, pain and appearance compared with sutures. Non-absorbable staples had an increased risk of skin separation and, therefore, reclosure. Skin separation was defined differently across trials and removal of staples varied from about day three to day seven postoperatively.

There is not enough evidence from the included studies to say which method of closing the caesarean skin incision is superior. Too few trials compared different kinds of sutures. The use of prophylactic antibiotics to reduce infection was not reported in most trials.

BACKGROUND

Caesarean section is the most common major surgery in many developed countries, and is performed on tens of millions of women annually worldwide. It is, therefore, paramount that this laparotomy be performed following the best technique. Several randomized trials have evaluated the safety and effectiveness of many technical aspects of caesarean (Berghella 2005).

Description of the condition

Caesareans are started by using a vertical or transverse suprapubic skin incision (a horizontal cut just above the pubic bone), with the Joel-Cohen method preferred (Hofmeyr 2008; Mathai 2007). After the skin incision is made, different techniques may be used to reach the uterus. Some obstetricians dissect their way to the uterus with a knife and scissors, others bluntly tear away the tissues. An opening on the uterus is typically via a low-transverse incision. This incision is extended bluntly with fingers (Dodd 2008). After delivery of the baby, the placenta should be removed spontaneously, with gentle cord traction and uterine massage (Anorlu 2008). External-abdominal repair of the uterus is associated with similar outcomes as intra-abdominal repair (Jacobs-Jokhan 2004). Single-layer closure compared with double-layer closure has been associated with a statistically significant reduction in mean blood loss; duration of the operative procedure; and presence of postoperative pain, but there are insufficient data to assess differences in single- versus double-layer closure in terms of long-term outcomes (e.g., chance of uterine rupture in a subsequent pregnancy) (Dodd 2008). The rectus muscle fascia is repaired next. This layer gives the whole wound its strength. If it is repaired incorrectly, the woman is at risk of developing an incisional hernia. Closure of the subcutaneous fat may reduce wound complications, especially in women with at least 2 cm of fat layer (Anderson 2004).

Description of the intervention

The skin layer, which is the subject of this review, can be repaired by subcuticular absorbable stitch (immediately below the skin layer), a non-absorbable interrupted stitch (individual stitches, typically placed transdermally), or absorbable or non-absorbable skin staples. A survey of skin closure techniques used in the UK (Tully 2002) showed that the subcuticular skin stitch was the most commonly used (74%) followed by interrupted skin stitch (8%) and others (18%). While this survey suggests little variation in surgical technique within the UK, different situations may apply in other countries.

How the intervention might work

Suture materials currently available are natural or synthetic, absorbable or non-absorbable, single-filament or braided. Until recently, catgut and silk were the two main natural sutures used in obstetrics. Catgut is made by treating strips of a sheep's small intestine with formaldehyde. It is an absorbable suture, but has been withdrawn from use in the UK due to the risk of cross infection with slow viruses. It was rarely used in skin closure.

With a growing choice of techniques and materials to use at skin closure, the effectiveness of the type of stitch and material used is unclear.

In theory, staples are attractive because of speed of application (Gatt 1985) and studies have shown mixed results when comparing wound pain and cosmesis between these two closure techniques (Eldrup 1981; Frishman 1997; Gaertner 2008; Ranabaldo 1992; Rousseau 2009).

Why it is important to do this review

With the wide variety of materials and techniques used at skin closure in caesareans, there is a need to identify which provide the best outcomes for women. This systematic review was conducted to identify evidence regarding the most effective skin closure techniques. Trials from general surgery can provide some information on the possible effects of the use of different techniques and materials, but it is important to analyze these interventions separately for caesareans.

OBJECTIVES

To compare the effects of skin closure techniques and materials on maternal outcomes and time taken to perform a caesarean.

METHODS

Criteria for considering studies for this review

Types of studies

All randomized comparisons of skin closure techniques in caesareans. Quasi-randomized studies were excluded.

Types of participants

Women undergoing a caesarean.

Types of interventions

The various combinations of closure techniques and materials were examined: absorbable subcuticular suture versus non-absorbable staples (primary comparison); absorbable subcuticular suture (polyglycolic acid) versus non-absorbable interrupted suture (nylon); subcuticular barbed suture versus subcuticular polydiaxanone suture (PDS); non-absorbable staples versus absorbable staples; non-absorbable suture versus a skin closure device (Leukosan SkinLink).

Types of outcome measures

Primary outcomes

1. Wound infection: includes surgical site infection and cellulitis requiring antibiotics as defined by trialists

Secondary outcomes

1. Wound complications (wound infection, hematoma, seroma, reclosure, readmission for wound complication)
2. Presence of hematoma (a collection of blood beneath the skin)
3. Presence of seroma (a collection of serous fluid beneath the skin)
4. Skin separation
5. Reclosure of the skin incision was required
6. Readmission for wound concern
7. Length of stay on readmission for wound concern
8. Pain perception (10-point scale): three to four days and six weeks postoperatively

9. Cosmesis (Observer Scar Assessment Scale (OSAS) and Patient Scar Assessment Scale (PSAS)) at two and six months postoperatively
10. Patient satisfaction (10-point scale): three to four days, six to eight weeks and six months postoperatively
11. Length of scar (centimeters)
12. Total operative time (minutes)
13. Cost (dollars)
14. Maternal length of hospital stay (days)
15. Presence of hypertrophic scar (keloid or hard prominent and irregular scar tissue) at six months and one year

Unless otherwise stated, the above outcomes were as defined by trialists. Outcome data that were not prespecified by the review authors, but were reported by the trial authors, are labeled as 'not specified' in the analysis and conclusions are based on prespecified outcomes.

Search methods for identification of studies

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (10 January 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searched the register for each review using the topic list rather than keywords.

We did not apply any language restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous version of this review, *see* Appendix 1.

For this update, we used the following methods when assessing the reports identified by the updated search.

Selection of studies

Two review authors independently assessed for inclusion all the potential studies that we identified as a result of the search strategy. There was no disagreement, but we planned to resolve any disagreement through discussion or, if required, we would have consulted the third author.

Data extraction and management

We designed a form to abstract data. For eligible studies, at least two review authors abstracted the data using the agreed form. We resolved discrepancies through discussion and, if required, planned to consult the third author. We entered data into Review Manager software (RevMan 2011) and double checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). There was no disagreement, but we planned to resolve any disagreement through discussion, or if required, we would have consulted the third author.

(1) Random sequence generation (checking for possible selection bias)

We described, for each included study, the method used to generate the allocation sequence, in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomization; consecutively numbered sealed opaque envelopes);
- high risk of bias (e.g. open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3) Blinding of participants and personnel (checking for possible performance bias) and Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results.

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a

participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low risk of bias (e.g. blinded outcomes assessors);
- high risk of bias (e.g. unblinded outcomes assessors);
- unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or was supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed methods as:

- low risk of bias (e.g. less than 30% missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomization, failure to apply intention-to-treat analysis);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we have about other possible sources of bias, including those related to study design, early cessation of study due to unplanned interim analyses, and extreme baseline imbalance.

We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we used the mean difference, if outcomes were measured in the same way between trials. We planned to use the standardized mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomized trials

We planned to include cluster-randomized trials in the analyses along with individually-randomized trials. There were no such trials. In future versions of this review, we will include cluster-randomized trials in the analyses along with individually-randomized trials. We will adjust their sample sizes using the methods described in the *Handbook* Section 16.3.4, using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomized trials and individually-randomized trials, we plan to synthesize the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomization unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomization unit and perform a sensitivity analysis to investigate the effects of the randomization unit.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analyses.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomized to each group in the analyses, and all participants were analyzed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomized minus any participants whose outcomes were known to be missing.

We planned to exclude trials in which 30% of participants were not closed by the method to which they were allocated; but there were none. We planned to and performed sensitivity analyses and excluded trials in which missing data exceeded 30%.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if T^2 is greater than zero and either I^2 is greater than 30% or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies that contribute data in the next update of the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by Egger 1997; and for dichotomous outcomes we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e., where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.

When we used random-effects analyses, the results were presented as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

We did not identify substantial heterogeneity in this analysis. Although exclusion criteria differed between the studies, we felt that the clinical populations were homogenous enough to warrant a fixed-effect approach, overall. If we identify substantial heterogeneity in the next update of the meta-analysis, we plan to investigate it using subgroup analyses and sensitivity analyses.

We planned to carry out the following subgroup analyses.

1. Caesareans performed by type of incision
2. Caesareans performed with preoperative antibiotics versus no preoperative antibiotics
3. Based on body mass index (BMI): >= 30 kg/m^2 and < 30 kg/m^2
4. Based on caesarean as related to labor: prior to labor versus after the onset of labor
5. Caesarean performed with chorioamnionitis verus without chorioamnionitis

The following outcomes were used in subgroup analysis: wound infection and composite wound complications.

For fixed-effect inverse variance meta-analyses, we assessed differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

If risk of bias was high, we excluded those studies and performed a sensitivity analysis.

RESULTS

Description of studies

See tables of Characteristics of included studies and Characteristics of excluded studies for details.

Methods and techniques

The majority of the studies compared non-absorbable staples versus absorbable sutures: monofilament (Basha 2010; Cromi 2010; Rengerink 2011; Rousseau 2009), braided (Cromi 2010; Gaertner 2008) and polyglycolic acid (Frishman 1997). Roungsipragarn 2001 compared polyglycolic acid subcuticular absorbable suture with non-absorbable nylon interrupted suture. Myers 2006 compared absorbable staples with non-absorbable staples. Murtha 2006 compared continuous subcuticular closure with barbed suture versus polydioxanone suture. Tan 2008 compared absorbable monofilament poliglecaprone suture with non-absorbable monofilament polypropylene suture. Juergens 2011 compared non-absorbable monofilament with a skin closure device.

Participants

For the primary comparison of non-absorbable staples versus absorbable sutures, six studies reported on outcomes on which this review focused, comprising 916 women (Basha 2010; Cromi 2010; Frishman 1997; Gaertner 2008; Rengerink 2011; Rousseau 2009).

Results of the search

We identified 19 studies as potentially eligible for inclusion and included 11, but only eight contributed data.

Included studies

We included 11 studies in the analysis: six in the primary comparison of staples versus absorbable suture (Basha 2010; Cromi 2010; Frishman 1997; Gaertner 2008; Rengerink 2011; Rousseau 2009), one that compared subcuticular suture versus interrupted suture (Roungsipragarn 2001), one that compared barbed suture versus polydiaxanone suture (PDS) (Murtha 2006), one that compared absorbable staples versus non-absorbable staples (Myers 2006), one that compared absorbable monofilament poliglecaprone suture with non-absorbable monofilament polypropylene suture (Tan 2008), and

one that compared monofilament polypropylene suture to a skin closure device (Juergens 2011). However, two studies that met the inclusion criteria did not report sufficiently on prespecified outcomes on which this review was focused (Myers 2006; Juergens 2011), and one study did not report outcomes separately for women undergoing caesarean (Tan 2008). Therefore, only eight of the 11 included trials contributed data.

Of the studies included in the primary comparison with outcomes on which this review was focused, five of the six limited the inclusion to women undergoing caesarean via Pfannenstiel incision (Cromi 2010; Frishman 1997; Gaertner 2008; Rengerink 2011; Rousseau 2009). Authors of four trials (Basha 2010; Cromi 2010; Gaertner 2008; Rengerink 2011) clarified or provided additional information to that which was included in the publications.

Excluded studies

Three studies were excluded as the participants were not randomized (Bohman 1994; Croce 2007; G-Calvillo 1999). One study was excluded as the comparison was between sutures and sutures with drain placement (Ramsey 2005). One study was excluded as the study has been terminated and data have not been published nor are available for review (Schnatz 2008). Two studies are ongoing and were listed as such (Grivell 2010; Tasillo 2008) (Characteristics of ongoing studies).

Risk of bias in included studies

Myers 2006 was only available as an abstract and there was only limited information available to assess risk of bias; there was not enough information in the abstract for outcomes specified in this review and the authors were unable to provide additional data. Tan 2008 did not report outcomes separately for women undergoing cesarean. Therefore, the following information refers to the remainder of the included studies. Of note, in Cromi 2010, there were a number of women lost to follow-up for assessment of cosmesis by patient and physician at six months.

Allocation

Basha 2010; Cromi 2010; Rousseau 2009; Juergens 2011 all used computer-generated randomization to generate sequences. Random sequence generation was not described for the following trials: Frishman 1997; Gaertner 2008; Murtha 2006; Rengerink 2011; Roungsipragarn 2001.

Basha 2010, Frishman 1997, Gaertner 2008, and Rousseau 2009 specified opaque, sealed envelopes. Murtha 2006 and Rengerink 2011 specified using envelopes. Juergens 2011 specified that patient numbers were randomly allocated to closure technique, but it is unclear whether the assignments were concealed prior to randomization. Cromi 2010 and Roungsipragarn 2001 did not specify method of allocation concealment.

Blinding

Neither participants nor personnel performing the closure were blinded in any of the studies and this did not factor into the determination of level of risk of bias. Some studies blinded the healthcare professional assessing the primary outcome (Cromi 2010; Murtha 2006; Rengerink 2011; Rousseau 2009). Frishman 1997 and Gaertner 2008 did not blind the healthcare professional assessing the primary outcome. Basha 2010 did not mention whether the outcomes assessor was blinded. Roungsipragarn 2001 did not describe the method used. Juergens 2011 had unblinded participants and physicians assess the incisions as well as blinded independent examiners assess photographs of the incision.

Incomplete outcome data

In Basha 2010, there were five women excluded after randomization who were not included in the analysis and, therefore, intention-to-treat analysis was not performed. All studies that contributed data (Basha 2010; Cromi 2010; Frishman 1997; Gaertner 2008; Murtha 2006; Rengerink 2011; Roungsipragarn 2001; Rousseau 2009) accounted for the number of women available for follow-up. However, in Gaertner 2008, there was a high rate of loss to follow-up. Juergens 2011 reported there were 12 women lost to follow-up, but it is unclear at what point in the study they were no longer included in the outcomes.

Selective reporting

Prespecified outcomes were stated in all studies that contributed data (Basha 2010; Cromi 2010; Frishman 1997; Gaertner 2008; Murtha 2006; Rengerink 2011; Roungsipragarn 2001; Rousseau 2009).

Other potential sources of bias

Basha 2010 performed an unplanned interim analysis and stopped the study early secondary to this analysis. Otherwise, there were no other potential sources of bias identified.

Effects of interventions

The following outcomes were not assessed in any of the included trials: length of stay on readmission, length of scar, cost, maternal length of hospital stay, and presence of hypertrophic scar at one year.

Non-absorbable staples versus absorbable suture

Six trials compared non-absorbable staples to absorbable suture (Basha 2010; Cromi 2010; Frishman 1997; Gaertner 2008; Rengerink 2011; Rousseau 2009) with 916 women. Of these six studies, five limited inclusion to women undergoing caesarean via Pfannenstiel incision and these five were included in a subgroup analysis (Cromi 2010; Frishman 1997; Gaertner 2008; Rengerink 2011; Rousseau 2009).

Primary outcomes

There were no significant differences in wound infection between the two groups (risk ratio (RR) 0.85; 95% confidence interval (CI) 0.43 to 1.71; Analysis 1.1). This was true even for the subgroup analysis for caesareans performed via Pfannenstiel skin incisions (RR 0.41; 95% CI 0.12 to 1.36; Analysis 1.1).

Of note, there is significant heterogeneity between the two subgroups in Analysis 1.1 and Analysis 1.2 with I^2 values of 61% and 84%, respectively. Therefore, this suggests that staples may have a differential effect depending on the type of incision, vertical or Pfannenstiel.

Secondary outcomes

There was a significant difference with regards to skin separation and requiring reclosure of incision. Incisions closed with staples were more likely to be complicated by separation (RR 3.82; 95% CI 2.05 to 7.12; Analysis 1.5) and therefore require reclosure (RR

4.98; 95% CI 1.82 to 13.61; Analysis 1.6). However, it is important to note that the majority of the studies did not define a minimum width to meet the definition of separation. Basha 2010, which was the largest of the studies, defined separation as per the patient or medical record; they noted that this varied from small defects in the skin to separation of the entire wound. Also, it is difficult to assess whether the separation preceded another complication such as hematoma, or whether the reverse is true. We are also unable to determine in what percentage the separation could potentially be iatrogenic (as a result of the procedure), e.g., staples were removed early, secondary to suspicion of wound infection. The remainder of the secondary outcomes studied were not significantly different between the groups.

Of note, despite that Frishman 1997 and Rousseau 2009 rated pain on 10 cm scales, the pain scale at discharge (Analysis 1.8) and pain scale postpartum (Analysis 1.9) revealed great statistical heterogeneity (I^2 values of 88 and 98% respectively). Therefore, we feel that even the random-effects model may not be applicable and that the results of these two studies may be too heterogeneous to be combined.

Non-absorbable staples versus absorbable suture (Sensitivity analysis)

Of the six trials that compared non-absorbable staples to absorbable suture, Basha 2010 and Gaertner 2008 were excluded for the sensitivity analysis. Gaertner 2008 was excluded because of high rates of loss to follow-up: 53 out of 153 women. Basha 2010 was excluded secondary to risk of bias.

Primary outcomes

There were no significant differences in wound infection between the two groups (RR 0.72; 95% CI 0.17 to 3.01, Analysis 2.1), which included only caesareans performed via Pfannenstiel skin incisions.

Secondary outcomes

There were no significant differences in secondary outcomes between the two groups.

Subcuticular absorbable suture versus interrupted non-absorbable suture

One trial compared subcuticular suture versus interrupted suture (Roungsipragarn 2001).

Primary outcomes

Wound infection was not assessed in this study.

Secondary outcomes

Those closed with interrupted suture were more likely to have a hypertrophic scar at six months (RR 1.85; 95% CI 1.33 to 2.58; Analysis 3.1). The remainder of the secondary outcomes studied were not significantly different between the groups.

Barbed suture versus PDS suture

One trial compared barbed suture versus PDS (Murtha 2006).

Primary outcomes

There were no significant differences in wound infection between the two groups (RR 0.96; 95% CI 0.18 to 5.10; Analysis 4.1).

Secondary outcomes

There were no significant differences in secondary outcomes between the two groups.

Absorbable staples versus non-absorbable staples

One trial compared absorbable staples versus non-absorbable staples (Myers 2006), but did not include outcomes on which this review was focused. Additional information was provided by the authors, though applicable data were not available for this review.

Absorbable sutures versus non-absorbable sutures

One trial compared polypropylene (non-absorbable) suture and poliglecaprone (absorbable) suture (Tan 2008). However, the study did not separately analyze women who underwent caesareans, so did not contribute data to this meta-analysis.

Non-absorbable sutures versus skin closure device (Leukosan SkinLink)

One trial compared polypropylene (non-absorbable) suture and Leukosan SkinLink (Juergens 2011). The study noted one incident of skin separation in the Leukosan SkinLink group. Otherwise, the study did not report sufficiently on outcomes on which this review was focused, so could not be included in the analyses.

Subgroup analyses

Subgroup analyses could only be performed based on type of skin incision for caesarean (Pfannenstiel only versus Pfannenstiels and vertical incisions). There was not enough information presented regarding patient body mass index (BMI), relation of surgery to presence or absence of labor, and relation of surgery to presence or absence of chorioamnionitis for those planned subgroup analyses to have been performed.

DISCUSSION

Summary of main results

The two methods of skin closure for caesarean section that have been most often compared are non-absorbable staples and absorbable subcutaneous sutures. Compared with absorbable subcutaneous sutures, non-absorbable staples are associated with similar incidences of wound infection. The use of prophylactic antibiotics, known to affect this outcome, was not reported in most trials. Other important secondary outcomes, such as wound complications, were also similar between the groups in women with Pfannenstiel incisions. Compared with absorbable subcutaneous sutures, non-absorbable staples are associated with an increased risk of skin separation and, therefore, reclosure. However, skin separation was variably defined across trials. Moreover, removal of staples varied from about day three to day seven postoperatively.

There was insufficient evidence to compare absorbable subcuticular sutures versus non-absorbable interrupted sutures, subcuticular barbed sutures versus subcuticular PDS sutures, absorbable staples versus non-absorbable staples, and absorbable sutures versus non-absorbable sutures. No other trials assessing

different comparisons were identified. Therefore, there is also insufficient evidence to compare different kinds of sutures.

Overall completeness and applicability of evidence

Several outcomes were not reported in any of the published trials: length of stay on readmission, length of scar, cost, maternal length of hospital stay, and presence of hypertrophic scar at one year. There is insufficient evidence to report on women who had preoperative antibiotics, for BMI >= 30 and < 30, and for caesarean prior to labor versus after the onset of labor. It is also impossible to do a subanalysis based on day of removal of staples. Other technical aspects of caesarean can affect wound outcomes. For example, manual versus spontaneous delivery of the placenta (Anorlu 2008) and closure of the subcutaneous space (Anderson 2004). These were not standardized within or among the trials.

Quality of the evidence

Cromi 2010, Rengerink 2011, Murtha 2006, and Rousseau 2009 had an overall low risk of bias. Frishman 1997 reported on outcomes assessed by non-blinded observers and participants and did not adequately describe the randomization methods used, but otherwise had a low risk of bias. Gaertner 2008 similarly reported on outcomes assessed by non-blinded observers and participants and did not adequately describe the randomization methods used; however, 53 of the 153 enrolled women were lost to follow-up. Basha 2010 had an overall high risk of bias as an intention-to-treat analysis was not performed, the study was stopped early due to an unplanned interim analysis and it is unclear whether the outcomes assessor was blinded. Due to this, a sensitivity analysis was performed for the primary comparison of absorbable sutures versus non-absorbable staples excluding Basha 2010 and Gaertner 2008. Myers 2006 and Roungsipragarn 2001 did not provide enough evidence for the quality of evidence to be assessed. Tan 2008 overall had a low risk of bias, though they had significant lost to follow-up rates, therefore, introducing a high risk of bias in this category. Juergens 2011 overall had a low risk of bias, though the concealment of their allocation remains unclear and they did not report at what point participants were lost to follow up.

Potential biases in the review process

Though we contacted all applicable authors to determine the number of women with wound complications, only Gaertner 2008 and Basha 2010 were able to provide this information; however, Basha 2010 was only able to provide information with respect to infections and separation, not hematoma or seroma. Therefore, for example, in any of the included studies (except Gaertner 2008), a woman with a seroma and hematoma may have been counted as two wound complications, rather than one. For other outcomes, unpublished data were provided by two authors (Cromi 2010; Rengerink 2011). Exclusion of other unidentified unpublished data cannot be ruled out. With regards to the outcome of women's satisfaction, Cromi 2010 used a visual analogue scale (VAS) scale and Rousseau 2009 used a general satisfaction scale, though the authors did not confirm whether this was a 10-point scale similar to VAS.

Agreements and disagreements with other studies or reviews

No other comprehensive reviews on this topic have been recently published.

AUTHORS' CONCLUSIONS

Implications for practice

There is currently no conclusive evidence about how the skin should be closed after caesarean. Staples are associated with similar outcomes in terms of wound infection, pain and cosmesis compared to sutures; and these two are the most commonly studied methods for skin closure at caesarean. If staples are removed on day three, there is an increased incidence of skin separation and need for reclosure compared to absorbable sutures.

Implications for research

The evidence suggests that staples may have a differential effect depending on the type of incision, vertical or Pfannenstiel. Additional research is necessary to ascertain whether this is the case. There is still insufficient evidence to determine whether day of staple removal impacts on wound separation. There is also need for future studies that use pre-operative antibiotic prophylaxis routinely, spontaneous placental removal, and closure of subcutaneous space when more than 2 cm. More research is needed to assess the effect of body mass index and primary versus repeat caesarean.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team) and the Group's Statistical Adviser.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Basha 2010

Methods	Randomized controlled trial. Staples versus absorbable subcuticular suture.
Participants	430 women undergoing caesarean were randomized: 206 to staples and 224 to suture. 9 were lost to follow-up: 8 from the staple group and 1 from the subcuticular suture group. Exclusion criteria: < 24 weeks, fetal death.
Interventions	Surgical staples versus 4-0 subcuticular poliglecaprone (Monocryl) suture.
Outcomes	Primary: composite wound complication rate and patient satisfaction.
Notes	Stopped before planned recruitment, after unplanned interim analysis. Conducted from March 2008-May 2009.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence in blocks.
Allocation concealment (selection bias)	Low risk	Placed in sequentially numbered, opaque, sealed envelopes.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Neither participants nor physician were blinded. It is unclear whether the outcomes abstractor was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Number of dropouts stated, but intention-to-treat analysis was not performed. 5 women were excluded after randomization: 4 from suture group and 1 from staple group. These women were excluded from analysis. 9 were lost to follow-up for wound complication assessment: 1 from suture group and 8 from staple group. An additional 16 did not complete the satisfaction survey: 8 in each group.

Basha 2010 *(Continued)*

Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	High risk	Stopped before planned recruitment after unplanned interim analysis.

Cromi 2010

Methods	Randomized controlled trial. Staples versus 3 types of subcuticular suture.
Participants	180 women undergoing caesarean were randomized: 45 to staples, 90 to absorbable suture (monofilament or braided), 45 to non-absorbable monofilament. At 2 months, 22 were lost to follow-up: 5 from the staple group, 0 from the absorbable monofilament group, 12 from the non-absorbable monofilament group, and 5 from the absorbable braided suture group. At 6 months, 57 were lost to follow-up: 14 from the staple group, 13 from the absorbable monofilament group, 17 from the non-absorbable monofilament group, and 13 from the absorbable braided suture group. Exclusion criteria: non-Pfannenstiel incisions, history of keloids, previous transverse suprapubic scars, tattoos in the area, hypersensitivity to sutures, medical disorder possibly affecting skin healing.
Interventions	4 groups: surgical staples, absorbable 3-0 monofilament (Monosyn), non-absorbable 3-0 monofilament made of polyamide fibres (Dafilon), and a synthetic absorbable braided suture made of low-molecular-weight polyglycolic acid (Safil Quick).
Outcomes	Primary: POSAS - combined OSAS (Observer Scar Assessment Scale) and PSAS (Patient Scar Assessment Scale) at 6 months postoperatively.
Notes	For the purposes of our analysis, the data for those closed with absorbable sutures were combined (data were provided by the authors) and the non-absorbable suture (Dafilon) group was excluded. Conducted from October 2006-March 2008.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated block randomization in a 1:1 ratio.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Cosmetic outcome evaluated by blinded observer and by non-blinded participants.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of dropouts were stated. Of the 45 women whose incisions were closed with staples, 40 were available at 2 months and 31 at 6 months for outcome assessment. Of the 90 women whose incisions were closed with absorbable sutures, 85 were available at 2 months and 64 at 6 months for outcome assessment.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.

Cromi 2010 *(Continued)*

Other bias	Unclear risk	Approximately 30% of participants were lost to follow-up by 6 months.

Frishman 1997

Methods	Randomized controlled trial. Staples versus absorbable subcuticular suture.
Participants	66 women undergoing caesarean were randomized: 34 to the staple group and 32 to the subcuticular suture group. 16 were lost to follow-up: 9 from the staple group and 7 from the subcuticular suture group. There were 25 women analyzed in each group. Exclusion criteria: vertical incision.
Interventions	Staples versus 4-0 subcuticular polyglycolic acid suture.
Outcomes	Primary: 10 cm POSAS scale.
Notes	Conducted from July 1995 to January 1996.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomized block design, but further specifications were not available and random-sequence generation was not described.
Allocation concealment (selection bias)	Low risk	Placed in opaque, sealed envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	Cosmetic outcome evaluated by non-blinded observer and participant.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of dropouts stated: 16 were lost to follow-up by the 6-week postoperative assessment and were excluded from analyses.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

Gaertner 2008

Methods	Randomized controlled trial. Staples versus absorbable subcuticular suture.
Participants	153 women undergoing caesarean were randomized, of which 100 were available for analysis of long-term follow-up. Of these 100, 51 were randomized to staples and 49 to the sutures. 53 were lost to long-term follow-up.

Gaertner 2008 *(Continued)*

	Exclusion criteria: non-Pfannenstiel incisions, diabetes mellitus, infection, emergency caesarean delivery.
Interventions	Staples versus 3-0 subcuticular polyglactin (Vicryl rapide) suture. Each of these 2 groups was further randomized to closure or non-closure of the subcutaneous space.
Outcomes	Primary: physician assessment of skin scar cosmesis based on a scoring system developed by the authors and patient satisfaction at 4 months.
Notes	Enrollment started December 2003.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random-sequence generation not described.
Allocation concealment (selection bias)	Low risk	Placed in opaque, sealed envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	Cosmetic outcome evaluated by non-blinded observer. Pain, satisfaction and cosmesis were also evaluated by non-blinded participants.
Incomplete outcome data (attrition bias) All outcomes	High risk	Number of dropouts stated: 53 were lost to follow-up and were excluded from the analysis. The authors attributed this to occupational mobility among study participants.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

Juergens 2011

Methods	Randomized controlled trial. Polypropylene suture (Prolene) versus skin closure device (Leukosan SkinLink).
Participants	61 women undergoing primary caesarean were randomized: 30 to Prolene and 31 to Leukosan SkinLink, of which 49 women completed the study (23 in the Prolene group and 26 in the Leukosan SkinLink group). Exclusion criteria: known allergy to cyanoacrylates, formaldehyde or dressing strips, women suffering from impaired wound healing, dermatoses, keloid formation, adipositis, impaired blood clotting or diabetes.
Interventions	Polyprophylene suture (Prolene) versus Leukosan SkinLink (adhesive coated, perforated, non-woven textile strips). Deep sutures were placed in the subcutaneous fat layer and subdermal suture placed regardless of randomization group.
Outcomes	Primary: cosmesis per the patient, physician and blinded independent examiners. This was assessed using 100 mm VAS scales at time of removal of closure device or suture, at 3, 6 and 12 months. The in-

Juergens 2011 *(Continued)*

	dependent examiners reviewed photographs of the incisions. Women remained in the hospital 7 days postoperatively, but it is unclear when the closure device or suture was removed.
Notes	June 2007 - March 2009.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomised number system.
Allocation concealment (selection bias)	Unclear risk	Women were randomly allocated to one of the wound closure techniques by a statistical software program. The allocation was fixed electronically and a printed copy given to the investigator who used the printed random list in sequence order. It is unclear whether the assignments were concealed prior to randomization.
Blinding (performance bias and detection bias) All outcomes	Low risk	Cosmetic outcome evaluated by blinded observer and by non-blinded participants and physicians.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number lost to follow up stated: 12 women did not complete the study. However, it is unclear how many women were available for follow-up at each specified time point, i.e., 3, 6 and 12 months.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

Murtha 2006

Methods	Randomized controlled trial. Barbed suture versus polydioxanone suture (both subcuticular).
Participants	195 women undergoing caesarean were randomized, of which 188 were available for analysis: 127 closed with barbed suture and 61 with polydioxanone suture. Exclusion criteria: non-Pfannenstiel incisions, diabetes mellitus, allergic reaction, emergency caesarean delivery, fever, body mass index > 42 kg/meters squared, history of keloid, pre-eclampsia, immunosuppressive drug use, chronic alcohol or drug abuse, use of investigational device within 30 days and American Society of Anesthesiology class 3 or 4.
Interventions	Barbed suture versus 3-0 polydioxanone suture (PDS).
Outcomes	Primary: Skin scar cosmesis by Hollander score.
Notes	Did not evaluate staples. Period of enrollment is unclear.

Risk of bias

Bias	Authors' judgement	Support for judgement

Murtha 2006 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Before randomization, women were stratified based on primary or repeat caesarean in an allocation schema of 2 barbed to 1 control within each strata, though the random-sequence generation was not described.
Allocation concealment (selection bias)	Low risk	Closed envelopes.
Blinding (performance bias and detection bias) All outcomes	Low risk	Cosmetic outcome evaluated by blinded observer.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of dropouts stated: 195 women were enrolled, 188 randomized (7 not randomized secondary to operative considerations), 6 were ineligible after randomization, 2 were withdrawn by investigators after randomization and 6 were lost to follow-up - all were included in the analyses.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

Myers 2006

Methods	Randomized controlled trial. Absorbable staples versus metal staples.
Participants	114 women undergoing caesarean via Pfannenstiel were randomized.
Interventions	Absorbable staples (INSORB) versus non-absorbable metal staples. Sample sizes not provided.
Outcomes	Primary: VAS for participant pain and satisfaction with scar.
Notes	Did not evaluate suture closure. Abstract only. Conducted from December 2004 to October 2005.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Random-sequence generation not described.
Allocation concealment (selection bias)	Low risk	Sequentially numbered, opaque, sealed envelopes. (Information provided by an author.)
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described.

Myers 2006 *(Continued)*

Selective reporting (reporting bias)	High risk	No pre-specified outcomes stated.
Other bias	Unclear risk	Unclear as not enough information is provided to assess this.

Rengerink 2011

Methods	Randomized controlled trial. Staples versus absorbable subcuticular suture.
Participants	133 women were randomized: 31 were randomized to no closure of the subcutaneous fat layer and skin closure with staples, 33 women to no closure of the subcutaneous fat layer and skin closure with suture, 35 to closure of the subcutaneous fat layer and skin closure with staples and 33 to closure of the subcutaneous fat layer with and skin closure with suture. Women older than 18 years undergoing a first caesarean delivery via Pfannenstiel were eligible. Exclusion criteria: previous abdominal operation, diabetes or signs of infection during delivery.
Interventions	Staples (n = 66) versus 3-0 subcuticular poliglecaprone (Monocryl) suture (n = 66); and closure versus non-closure of subcutaneous space.
Outcomes	Primary: skin scar cosmesis at 6 months.
Notes	The authors provided additional information for inclusion in this review as only the abstract had been published thus far. Antibiotic prophylaxis was administered after delivery of the baby. Staples were removed on postoperative day 7. For the purpose of this analysis, data from those closed with staples were combined and those closed with suture were combined, regardless of closure or non-closure of the subcutaneous space. Conducted from February 2007 to October 2008.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Factorial design with 2 comparisons of 2 interventions, so each woman was randomized twice: 1) closure versus no closure of the subcutaneous fat layer, and 2) skin closure with staples versus intracutaneous skin closure.
Allocation concealment (selection bias)	Low risk	Sealed envelope.
Blinding (performance bias and detection bias) All outcomes	Low risk	Cosmetic outcome evaluated by blinded observer and by non-blinded participants.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of dropouts stated: allocation code was lost for 1 woman, 3 women were excluded (after randomization) as they would not have been eligible (secondary to diabetes) and 5 women were lost to follow-up, so 124 women were analyzed.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.

Rengerink 2011 *(Continued)*

Other bias	Low risk	No other potential sources of bias identified.

Roungsipragarn 2001

Methods	Randomized controlled trial. Polyglycolyc acid suture versus nylon suture.
Participants	80 women undergoing caesarean were randomized. 62 completed the trial: 32 were closed with polyglycolic acid suture and 30 with interrupted nylon suture. Exclusion criteria: not listed.
Interventions	2-0 polyglycolic acid suture versus transverse interrupted 0-nylon suture.
Outcomes	Primary: skin scar hypertrophy at 6 months.
Notes	Did not evaluate staples. Period of enrollment is unclear.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random-sequence generation not described.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	80 women entered the study and 62 completed the trial. No additional information provided.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

Rousseau 2009

Methods	Randomized controlled trial. Staples versus absorbable subcuticular suture.
Participants	101 women undergoing caesarean were randomized: 49 to staples and 52 to suture. 9 women were lost to follow-up: 4 from the staple group and 5 from the suture group.

Rousseau 2009 *(Continued)*

	Exclusion criteria: non-Pfannenstiel incisions, diabetes mellitus, BMI > 35, alcohol or drug abuse, contraindication to NSAID use postoperatively.
Interventions	Surgical staples versus 4-0 subcuticular poliglecaprone (Monocryl) suture.
Outcomes	Primary: compared postoperative pain immediately and at 6 weeks postpartum.
Notes	Conducted from February 2007 to January 2008.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number table in a block size of 8. Stratification based on primary or repeat caesarean.
Allocation concealment (selection bias)	Low risk	Placed in opaque, sealed envelopes.
Blinding (performance bias and detection bias) All outcomes	Low risk	Cosmetic outcome evaluated by blinded observers. Pain was assessed by unblinded participants.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number of dropouts stated: 9 women were lost to follow-up, but included in the analysis.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

Tan 2008

Methods	Randomized controlled trial. Absorbable monofilament poliglecaprone suture versus non-absorbable monofilament polypropylene suture.
Participants	213 women undergoing caesarean were randomized: 107 were randomized to the polypropylene (non-absorbable) suture and 106 to the poliglecaprone (absorbable) suture. Inclusion criteria: women without an abdominal scar who were scheduled to undergo benign gynecologic surgery or caesarean delivery using a Pfannenstiel incision.
Interventions	Absorbable monofilament poliglecaprone suture versus non-absorbable monofilament polypropylene suture.
Outcomes	Primary: wound experience as measured on a 10-point VAS scale at weeks 1 and 4 postoperatively.
Notes	Conducted from April 2006 and December 20078. Does not present information for caesarean surgeries separately, so data were not included in data analysis for this review.

Risk of bias

Tan 2008 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization in blocks of 10.
Allocation concealment (selection bias)	Low risk	Sealed and sequentially numbered opaque envelopes containing suture packets were prepared.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Participants were not blinded. It is unclear if providers who assessed wound infection were blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	At 1 week postoperatively, 145/213 women were evaluated. At 4 weeks, 97/213 women were evaluated.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes were stated.
Other bias	Low risk	No other potential sources of bias identified.

BMI: body mass index
NSAID: non-steroidal anti-inflammatory DRUG
OSAS: Observer Scar Assessment Scale
PDS: polydiaxanone suture
POSAS: Patient and Observer Scar Assessment Scale
PSAS: Patient Scar Assessment Scale
VAS: visual analogue scale

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Bohman 1994	Not a randomized controlled trial.
Croce 2007	Not a randomized controlled trial.
G-Calvillo 1999	Not a randomized controlled trial.
Ramsey 2005	Compares suture versus suture and drain.
Schnatz 2008	This study has been terminated and results not available for publication or review.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Avsar 2009

Methods
Participants
Interventions

Avsar 2009 *(Continued)*

Outcomes	
Notes	Turkish - translation not yet available.

Characteristics of ongoing studies *[ordered by study ID]*

Grivell 2010

Trial name or title	Closing the skin and subcutaneous layers at caesarean section to reduce wound complications.
Methods	Using a 2 x 2 factorial design, participants will be randomized to a) either closure or non-closure of the subcutaneous tissue and b) closure of the skin with a subcuticular monofilament non-absorbable versus absorbable suture. For both aspects of the procedure these are 2 currently used techniques, so there is no true intervention, only randomization to 2 currently used techniques.
Participants	Pregnant women undergoing caesarean via transverse suprapubic incision.
Interventions	Closure or non-closure of subcutaneous tissue and absorbable versus non-absorbable monofilament suture for closure of the skin.
Outcomes	Primary outcome: wound infection - as assessed by phone call at 30 days postoperatively and medical record review or return of wound assessment forms. Secondary outcome: wound hematoma and seroma.
Starting date	01/04/2008.
Contact information	Dr Rosalie Grivell; rosalie.grivell@adelaide.edu.au
Notes	

Tasillo 2008

Trial name or title	A comparative study of closure techniques after caesarean section: staples vs Dermabond.
Methods	Allocation: randomized. Endpoint classification: safety/efficacy study. Intervention model: single group assignment. Masking: open label. Primary purpose: treatment.
Participants	Pregnant women undergoing caesarean via non-vertical abdominal incisions.
Interventions	Staples vs Dermabond.
Outcomes	Primary outcome: wound complication rate at 6 weeks. Secondary outcome: patient satisfaction of cosmesis of surgical wound at 6 weeks.
Starting date	September 2007.
Contact information	
Notes	This study is ongoing, but not recruiting participants.

vs: versus

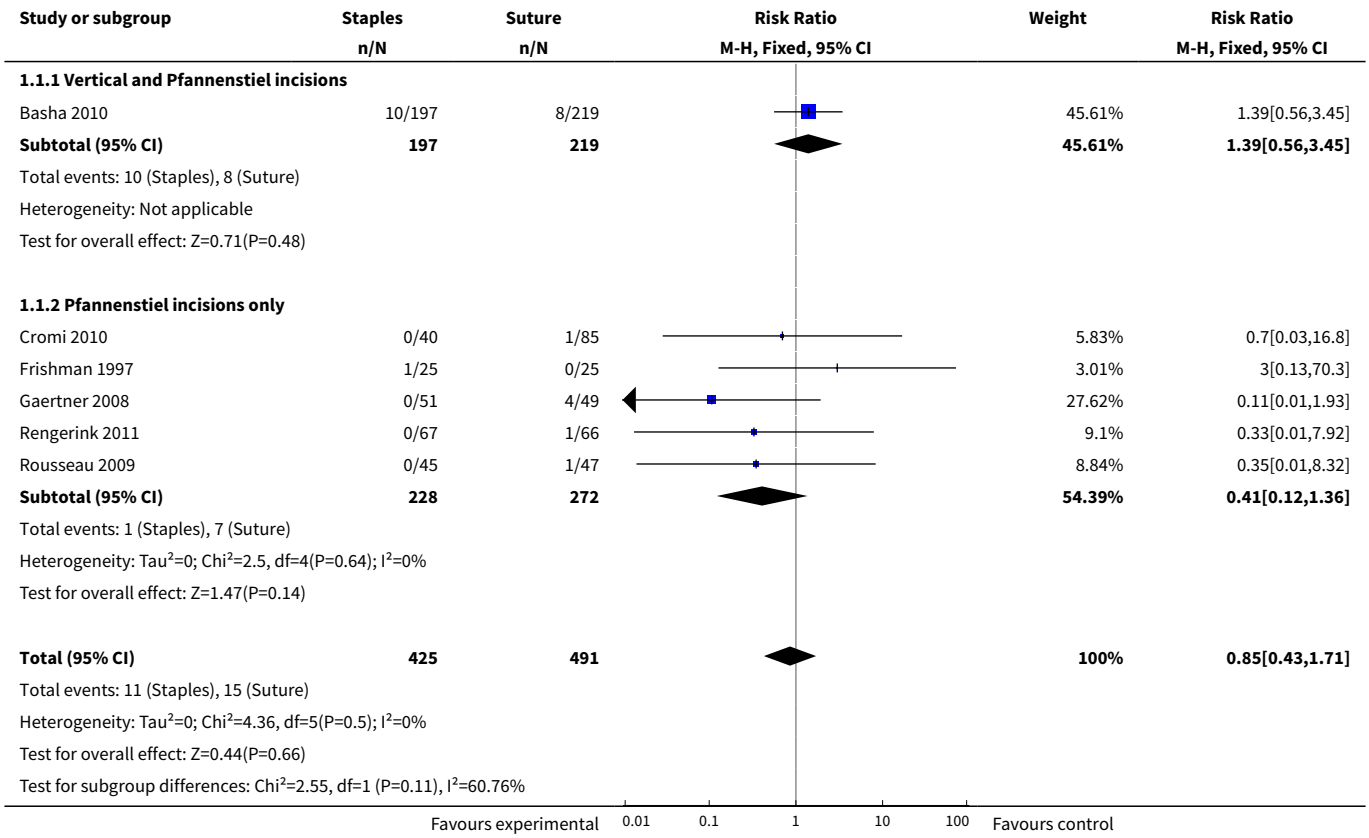
DATA AND ANALYSES

Comparison 1. Staples versus absorbable subcuticular suture

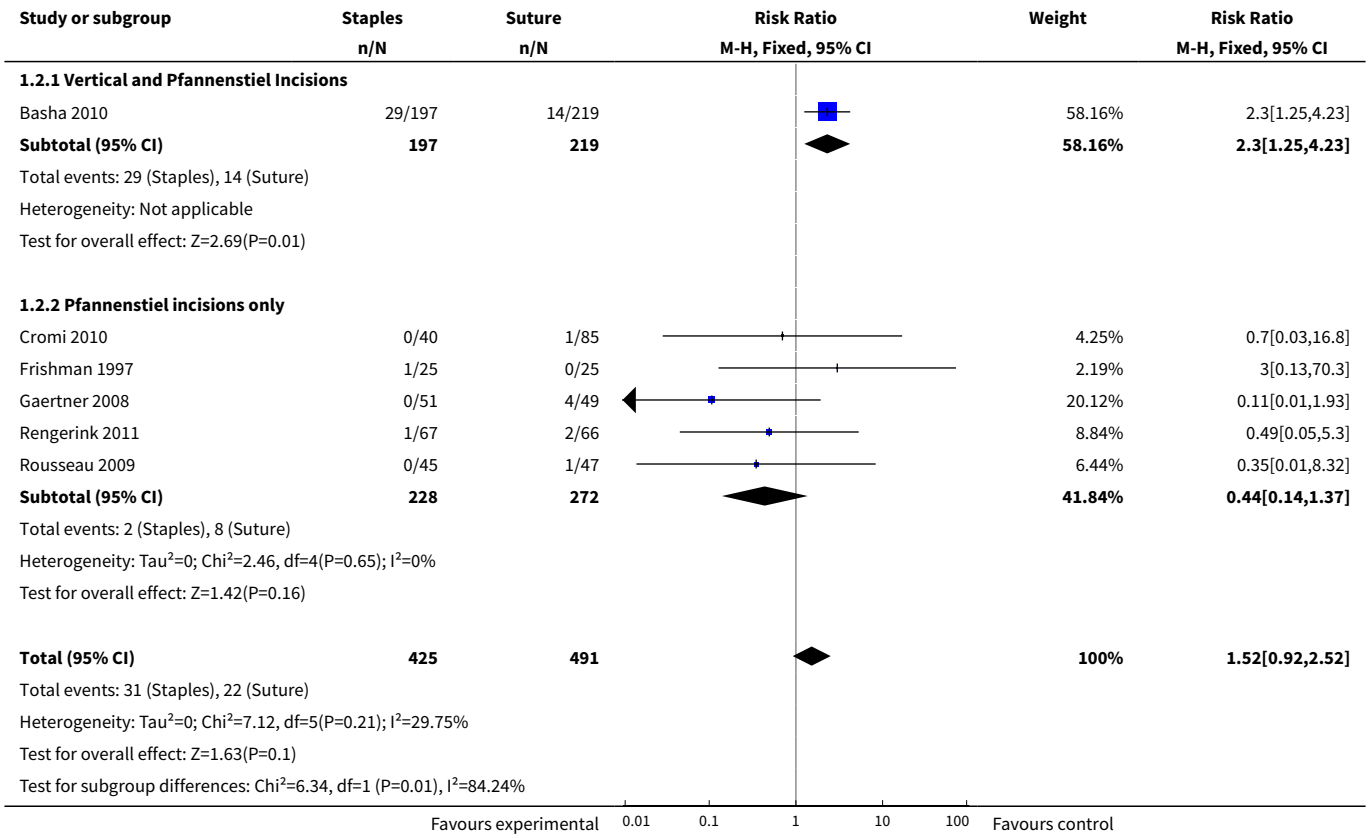
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Wound infection	6	916	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.43, 1.71]
1.1 Vertical and Pfannenstiel incisions	1	416	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [0.56, 3.45]
1.2 Pfannenstiel incisions only	5	500	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.12, 1.36]
2 Wound complications	6	916	Risk Ratio (M-H, Fixed, 95% CI)	1.52 [0.92, 2.52]
2.1 Vertical and Pfannenstiel Incisions	1	416	Risk Ratio (M-H, Fixed, 95% CI)	2.30 [1.25, 4.23]
2.2 Pfannenstiel incisions only	5	500	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.14, 1.37]
3 Presence of hematoma	3	283	Risk Ratio (M-H, Random, 95% CI)	1.32 [0.10, 18.39]
4 Presence of seroma	2	150	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.01, 7.68]
5 Skin separation	5	824	Risk Ratio (M-H, Fixed, 95% CI)	3.82 [2.05, 7.12]
6 Reclosure	2	516	Risk Ratio (M-H, Fixed, 95% CI)	4.98 [1.82, 13.61]
7 Readmission	1	416	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.05, 6.08]
8 Pain scale at discharge (10 cm scale): 3-4 days	2	148	Mean Difference (IV, Random, 95% CI)	0.57 [-1.20, 2.33]
9 Pain scale postpartum (10 cm): 6 weeks	2	145	Mean Difference (IV, Random, 95% CI)	0.59 [-1.17, 2.36]
10 Cosmesis per physician (OSAS) at 2 months	1	125	Mean Difference (IV, Fixed, 95% CI)	0.0 [-2.76, 2.76]
11 Cosmesis per physician (OSAS) at 6 months	2	228	Mean Difference (IV, Fixed, 95% CI)	1.69 [-0.44, 3.83]
12 Cosmesis per patient (PSAS) at 2 months	1	125	Mean Difference (IV, Fixed, 95% CI)	0.20 [-2.75, 3.15]
13 Cosmesis per patient (PSAS) at 6 months	2	226	Mean Difference (IV, Random, 95% CI)	0.75 [-2.08, 3.59]
14 Patient satisfaction (10 cm scale): at discharge	1	98	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-1.85, 0.25]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15 Patient satisfaction (10 cm scale): 6-8 weeks postoperatively	2	217	Mean Difference (IV, Random, 95% CI)	0.12 [-1.24, 1.49]
16 Patient satisfaction (10 cm scale): 6 months postoperatively	1	95	Mean Difference (IV, Fixed, 95% CI)	-0.5 [-1.17, 0.17]
17 Total operative time (minutes)	2	226	Mean Difference (IV, Random, 95% CI)	-5.74 [-12.49, 1.02]
18 Maternal length of stay (days)	1	416	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.01, 0.21]
19 Presence of hypertrophic scar at 6 months	1	95	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.58, 1.70]

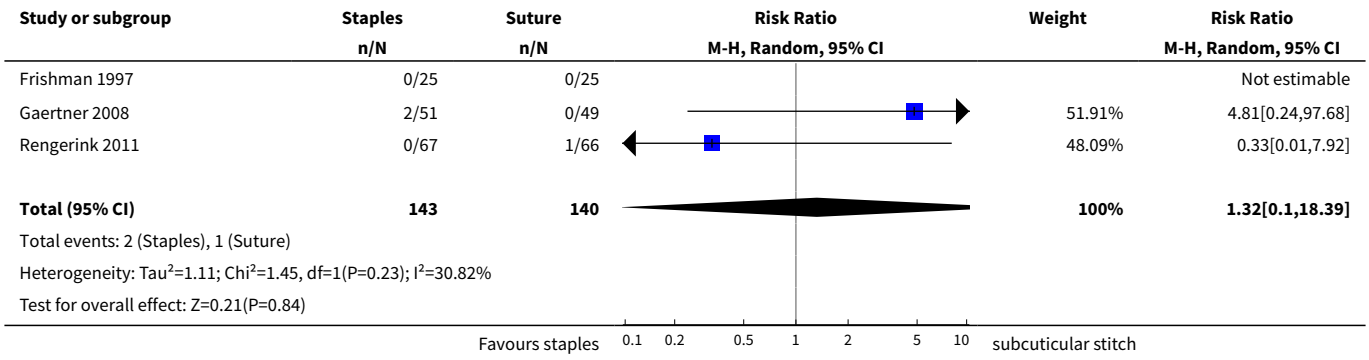
Analysis 1.1. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 1 Wound infection.



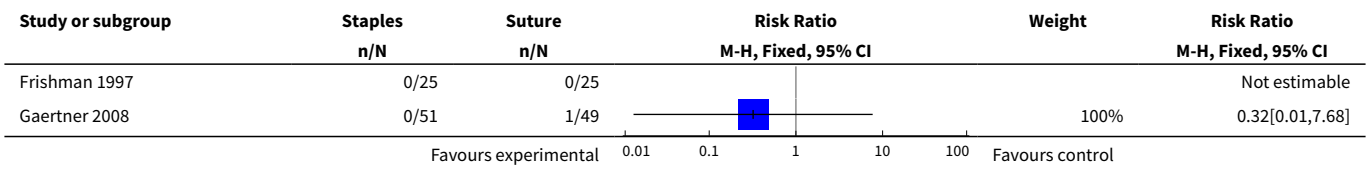
Analysis 1.2. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 2 Wound complications.

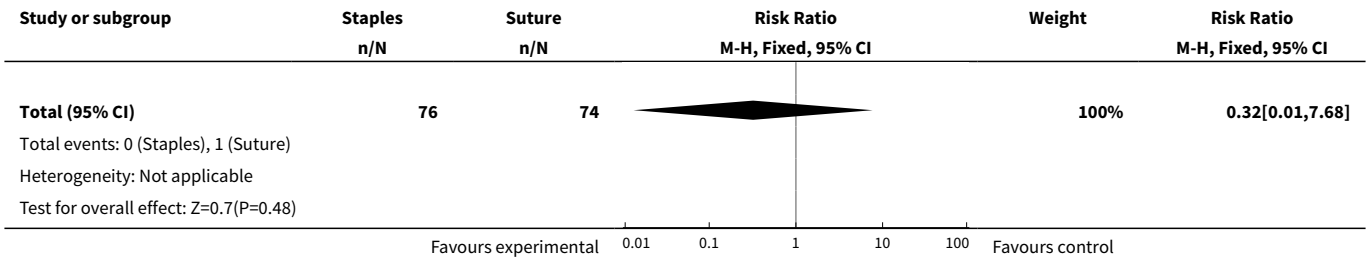


Analysis 1.3. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 3 Presence of hematoma.

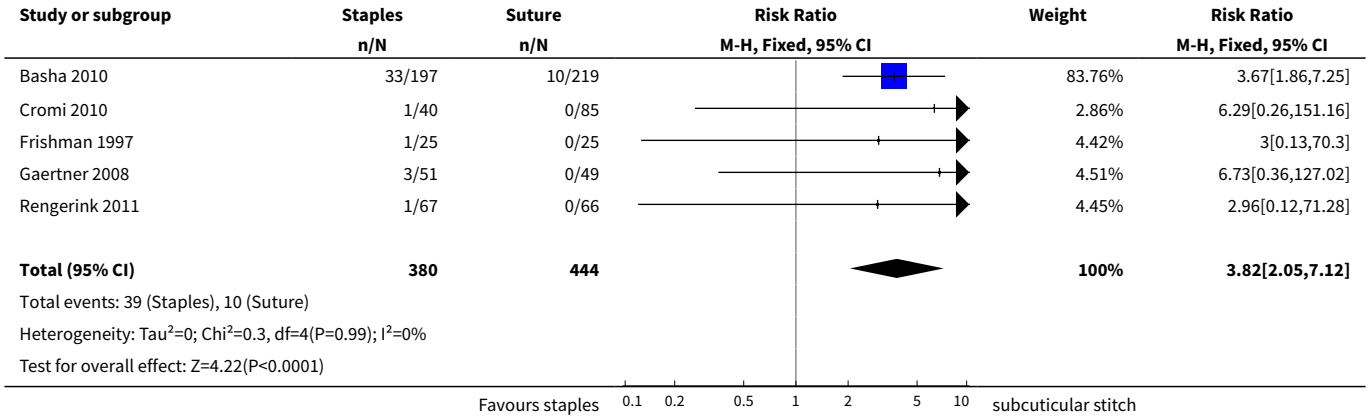


Analysis 1.4. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 4 Presence of seroma.

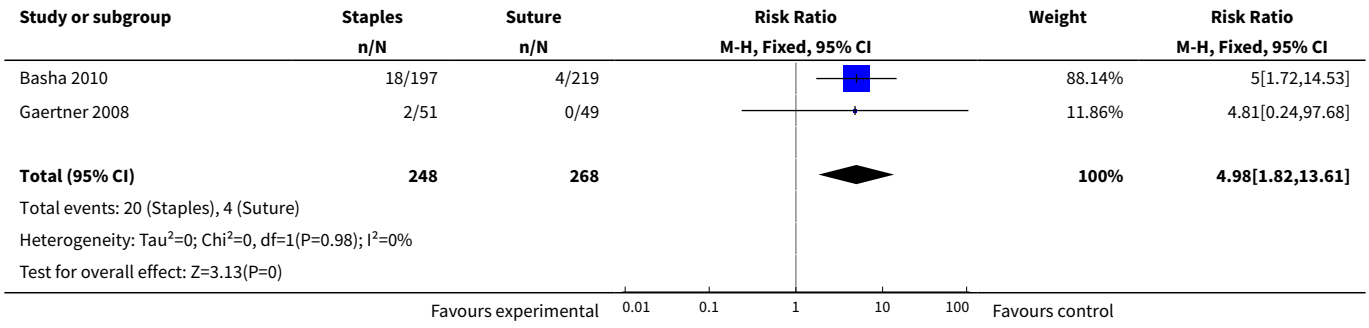




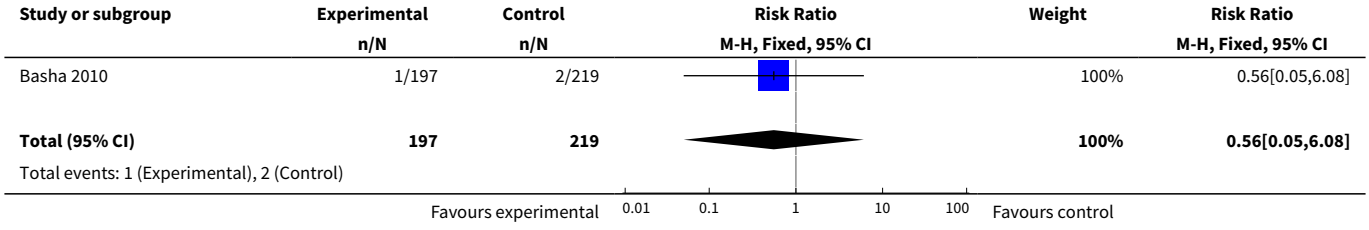
Analysis 1.5. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 5 Skin separation.

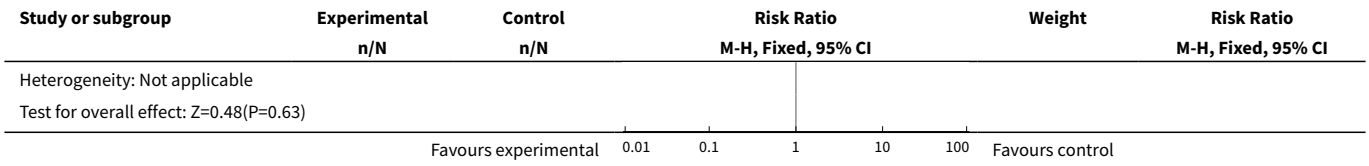


Analysis 1.6. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 6 Reclosure.

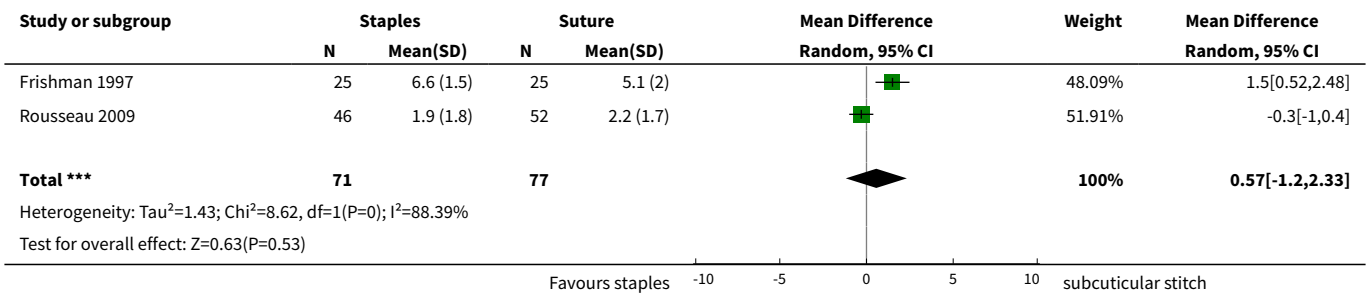


Analysis 1.7. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 7 Readmission.

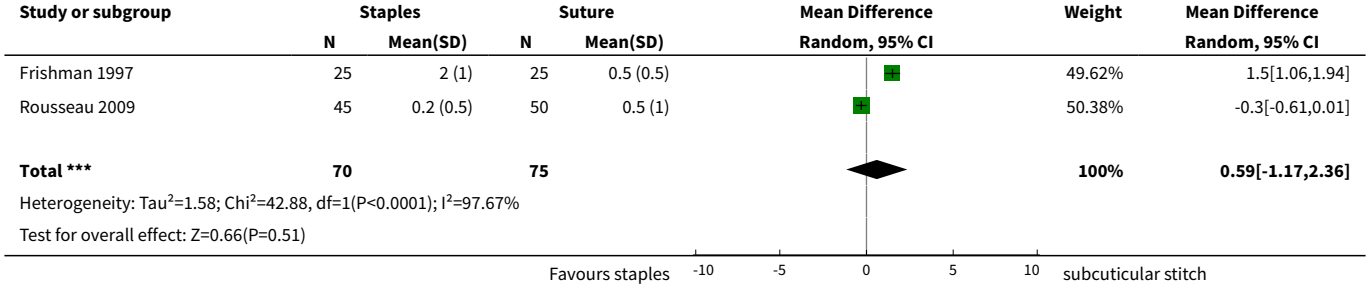




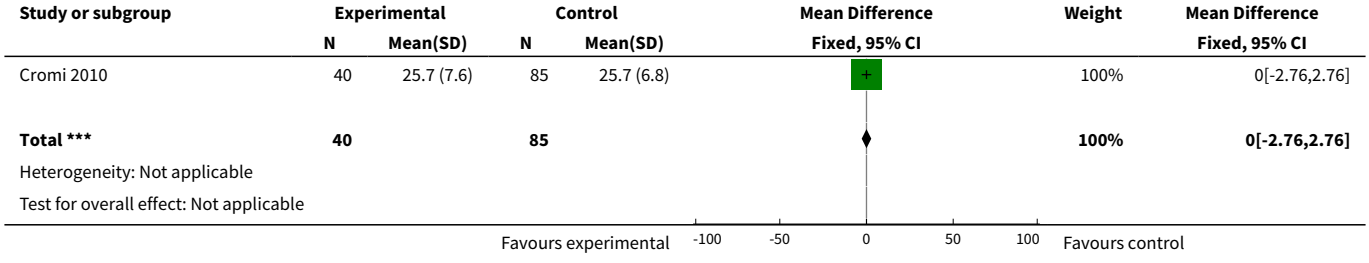
Analysis 1.8. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 8 Pain scale at discharge (10 cm scale): 3-4 days.



Analysis 1.9. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 9 Pain scale postpartum (10 cm): 6 weeks.



Analysis 1.10. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 10 Cosmesis per physician (OSAS) at 2 months.



Analysis 1.11. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 11 Cosmesis per physician (OSAS) at 6 months.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Cromi 2010	31	23.5 (8.1)	64	20.5 (7.3)		40.09%	3.03[-0.34,6.4]
Rengerink 2011	67	21.8 (8.1)	66	21 (8.1)		59.91%	0.8[-1.95,3.55]
Total ***	**98**		**130**			**100%**	**1.69[-0.44,3.83]**
Heterogeneity: Tau²=0; Chi²=1.01, df=1(P=0.31); I²=1.01%							
Test for overall effect: Z=1.56(P=0.12)							

Analysis 1.12. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 12 Cosmesis per patient (PSAS) at 2 months.

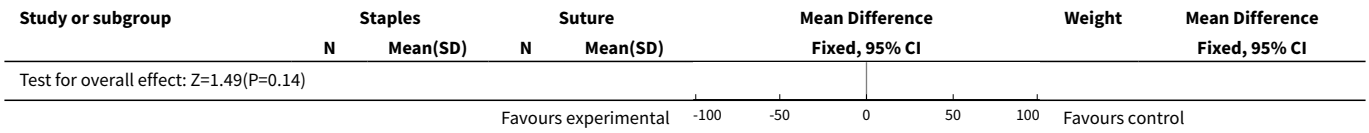
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Cromi 2010	40	21.8 (7.4)	85	21.6 (8.7)		100%	0.2[-2.75,3.15]
Total ***	**40**		**85**			**100%**	**0.2[-2.75,3.15]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.13(P=0.89)							

Analysis 1.13. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 13 Cosmesis per patient (PSAS) at 6 months.

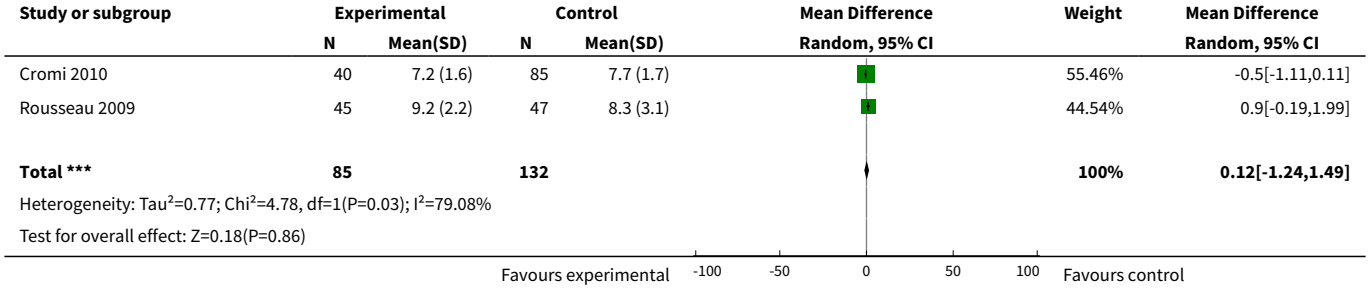
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Cromi 2010	31	22.6 (7.3)	64	20.5 (7.2)		53.51%	2.1[-1.02,5.22]
Rengerink 2011	67	25.7 (9.2)	64	26.5 (10.9)		46.49%	-0.8[-4.26,2.66]
Total ***	**98**		**128**			**100%**	**0.75[-2.08,3.59]**
Heterogeneity: Tau²=1.38; Chi²=1.49, df=1(P=0.22); I²=32.83%							
Test for overall effect: Z=0.52(P=0.6)							

Analysis 1.14. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 14 Patient satisfaction (10 cm scale): at discharge.

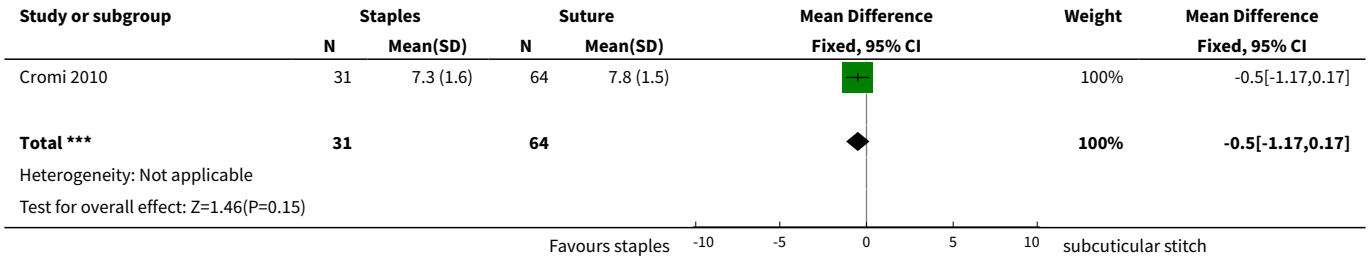
Study or subgroup	Staples N	Staples Mean(SD)	Suture N	Suture Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Rousseau 2009	47	7.2 (3.2)	51	8 (1.9)		100%	-0.8[-1.85,0.25]
Total ***	**47**		**51**			**100%**	**-0.8[-1.85,0.25]**
Heterogeneity: Not applicable							



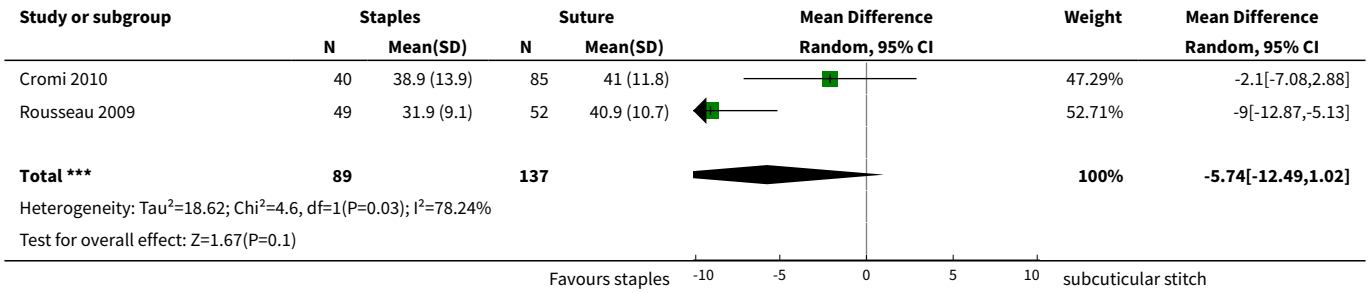
Analysis 1.15. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 15 Patient satisfaction (10 cm scale): 6-8 weeks postoperatively.



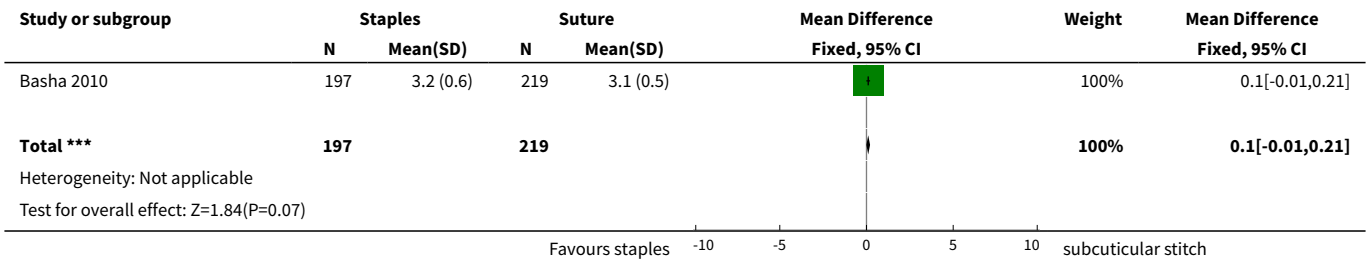
Analysis 1.16. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 16 Patient satisfaction (10 cm scale): 6 months postoperatively.



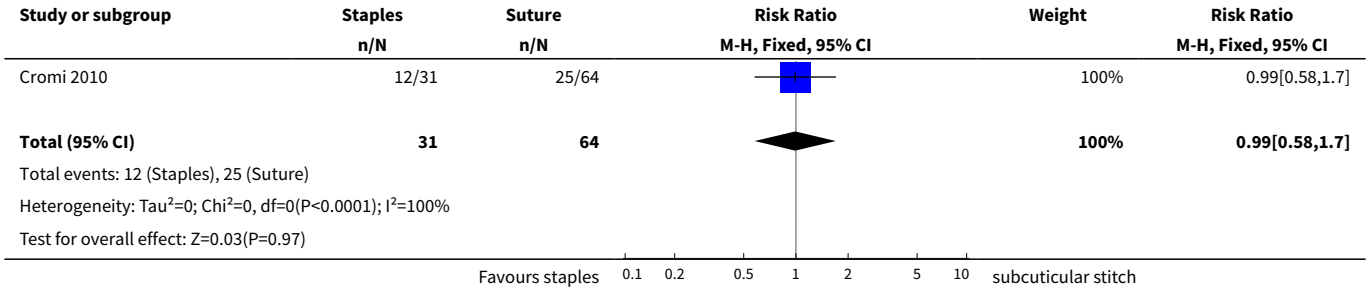
Analysis 1.17. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 17 Total operative time (minutes).



Analysis 1.18. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 18 Maternal length of stay (days).



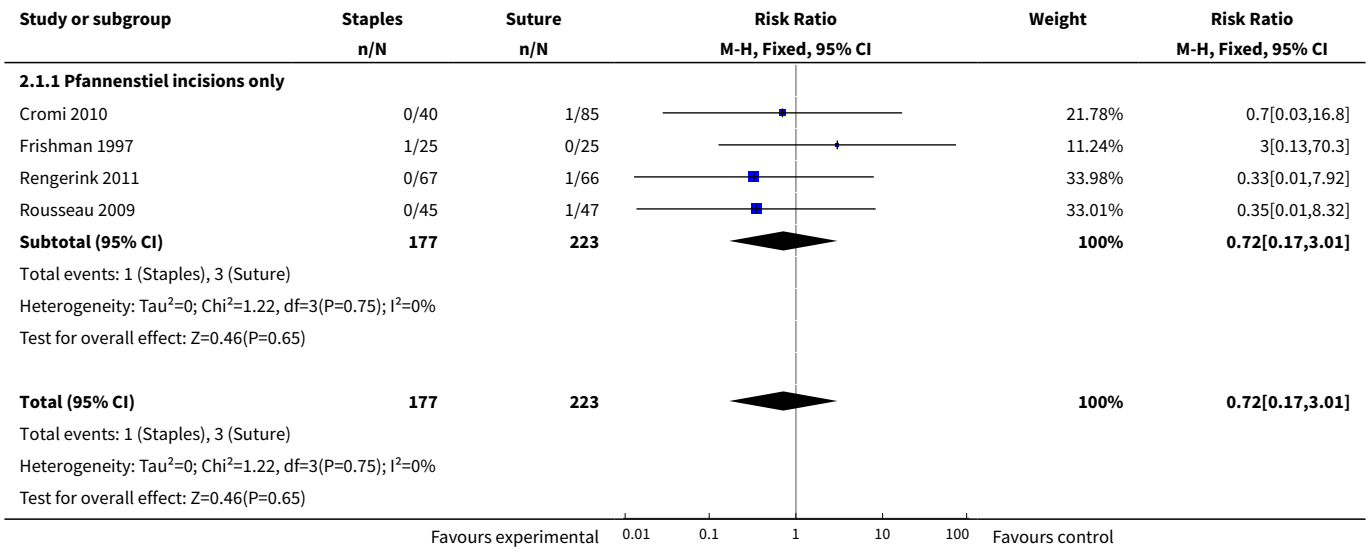
Analysis 1.19. Comparison 1 Staples versus absorbable subcuticular suture, Outcome 19 Presence of hypertrophic scar at 6 months.



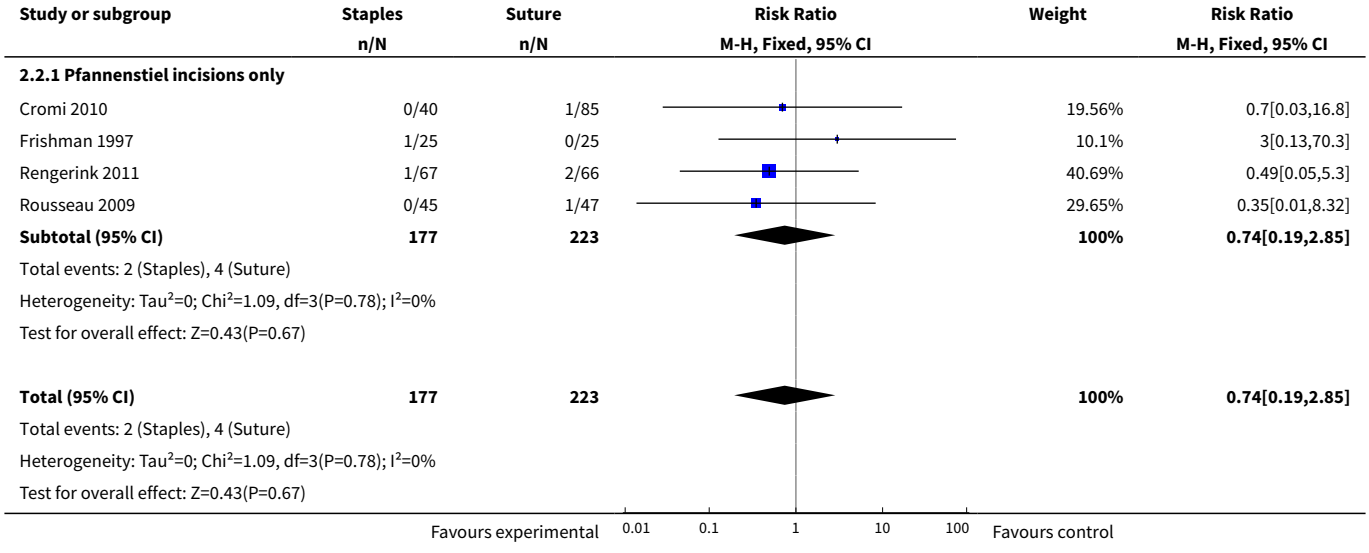
Comparison 2. Staples versus absorbable subcuticular suture (sensitivity analysis)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Wound infection	4	400	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.17, 3.01]
1.1 Pfannenstiel incisions only	4	400	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.17, 3.01]
2 Wound complications	4	400	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.19, 2.85]
2.1 Pfannenstiel incisions only	4	400	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.19, 2.85]
3 Presence of hematoma	2	183	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.01, 7.92]
4 Presence of seroma	1	50	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Skin separation	3	308	Risk Ratio (M-H, Fixed, 95% CI)	3.78 [0.62, 23.00]

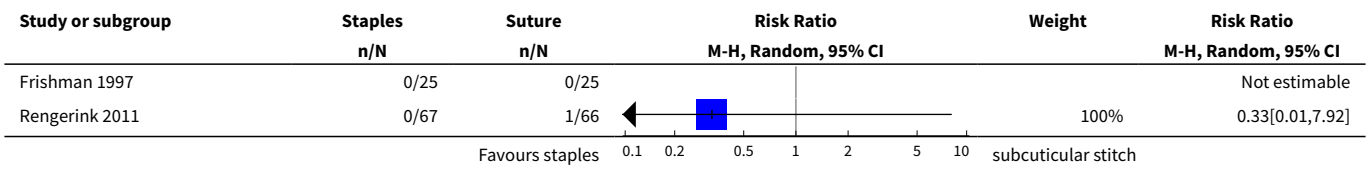
Analysis 2.1. Comparison 2 Staples versus absorbable subcuticular suture (sensitivity analysis), Outcome 1 Wound infection.

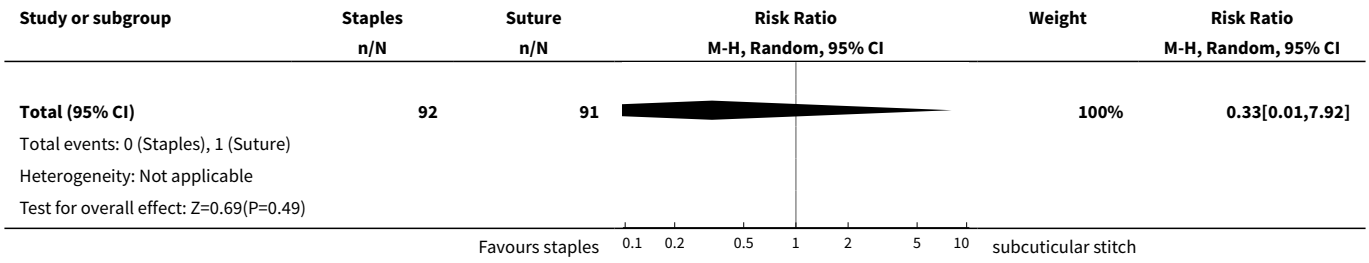


Analysis 2.2. Comparison 2 Staples versus absorbable subcuticular suture (sensitivity analysis), Outcome 2 Wound complications.

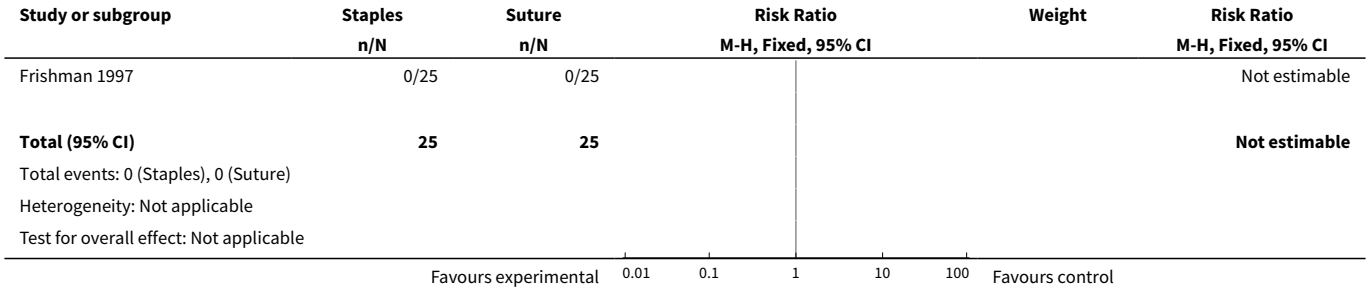


Analysis 2.3. Comparison 2 Staples versus absorbable subcuticular suture (sensitivity analysis), Outcome 3 Presence of hematoma.

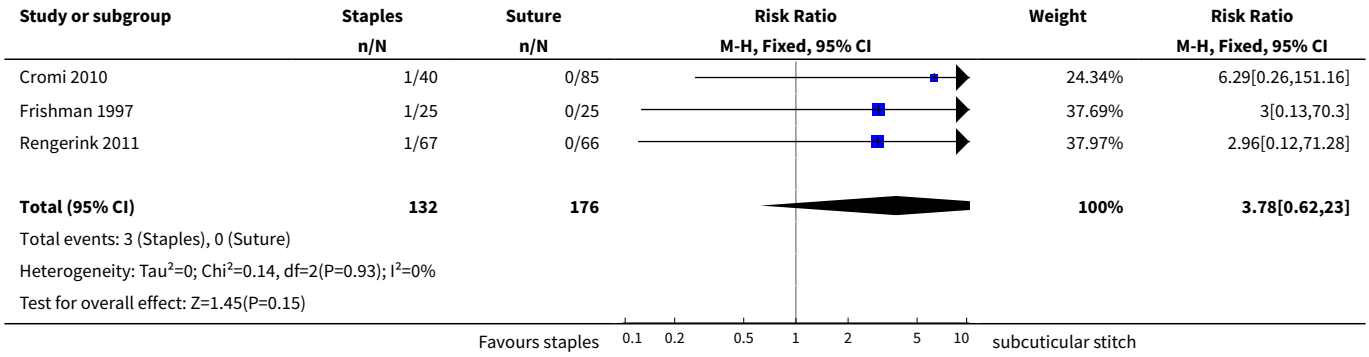




Analysis 2.4. Comparison 2 Staples versus absorbable subcuticular suture (sensitivity analysis), Outcome 4 Presence of seroma.



Analysis 2.5. Comparison 2 Staples versus absorbable subcuticular suture (sensitivity analysis), Outcome 5 Skin separation.



Comparison 3. Subcuticular suture versus interrupted suture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Presence of hypertrophic scar at 6 months	1	62	Risk Ratio (M-H, Fixed, 95% CI)	1.85 [1.33, 2.58]

Analysis 3.1. Comparison 3 Subcuticular suture versus interrupted suture, Outcome 1 Presence of hypertrophic scar at 6 months.

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Roungsipragarn 2001	32/32	16/30		100%	1.85[1.33,2.58]
Total (95% CI)	**32**	**30**		**100%**	**1.85[1.33,2.58]**
Total events: 32 (Experimental), 16 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=3.63(P=0)					

Favours experimental — Favours control

Comparison 4. Barbed suture versus PDS suture

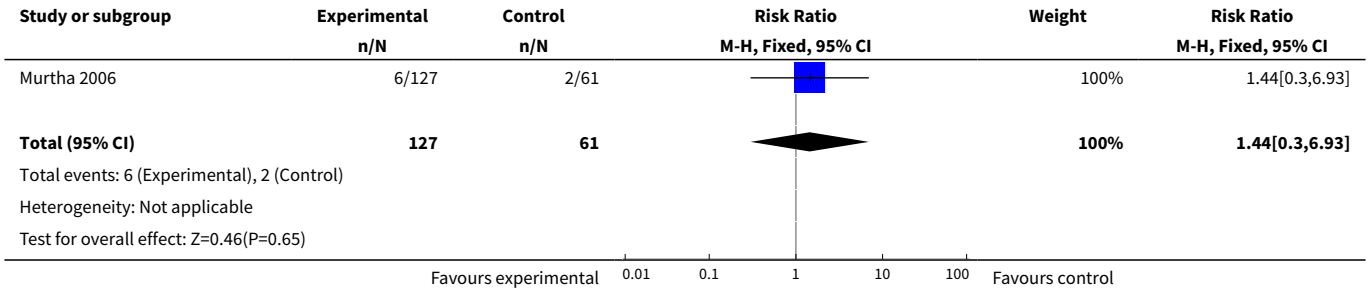
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Wound infection	1	188	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.18, 5.10]
2 Wound complications	1	188	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.30, 6.93]
3 Hematoma	1	188	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Seroma	1	188	Risk Ratio (M-H, Fixed, 95% CI)	2.42 [0.12, 49.69]
5 Skin separation	1	188	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Time to skin closure of dermal and epidermal layer (minutes)	1	188	Mean Difference (IV, Fixed, 95% CI)	0.60 [-0.30, 1.50]

Analysis 4.1. Comparison 4 Barbed suture versus PDS suture, Outcome 1 Wound infection.

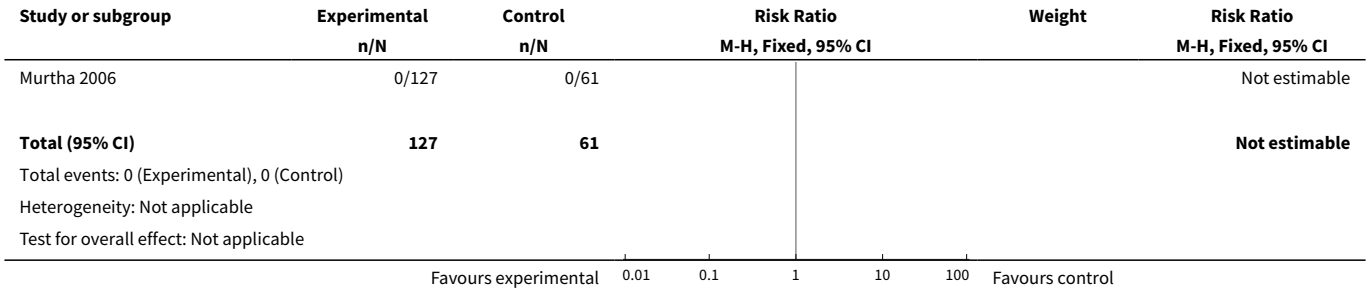
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Murtha 2006	4/127	2/61		100%	0.96[0.18,5.1]
Total (95% CI)	**127**	**61**		**100%**	**0.96[0.18,5.1]**
Total events: 4 (Experimental), 2 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%					
Test for overall effect: Z=0.05(P=0.96)					

Favours experimental — Favours control

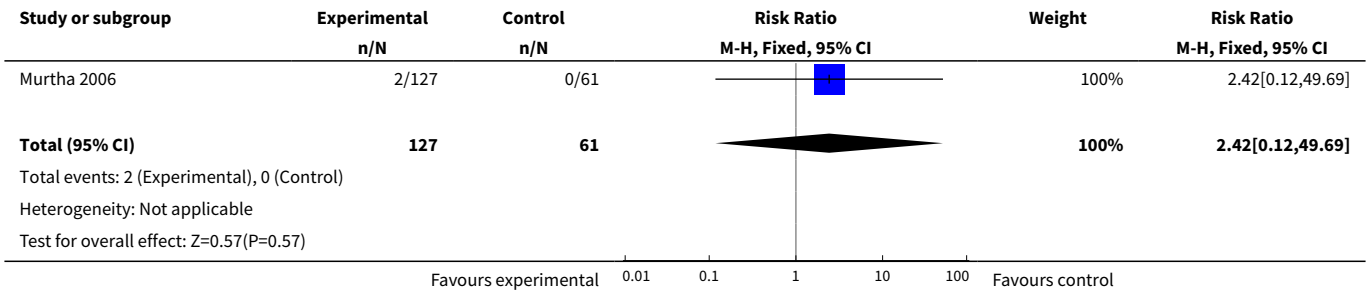
Analysis 4.2. Comparison 4 Barbed suture versus PDS suture, Outcome 2 Wound complications.



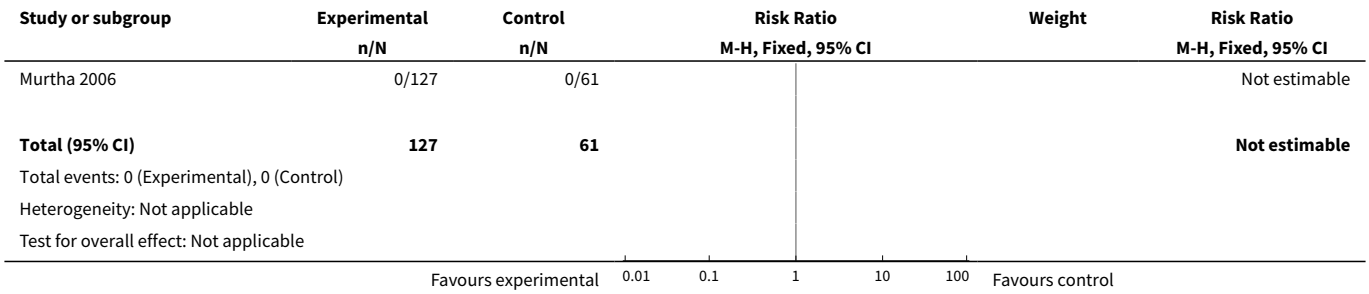
Analysis 4.3. Comparison 4 Barbed suture versus PDS suture, Outcome 3 Hematoma.



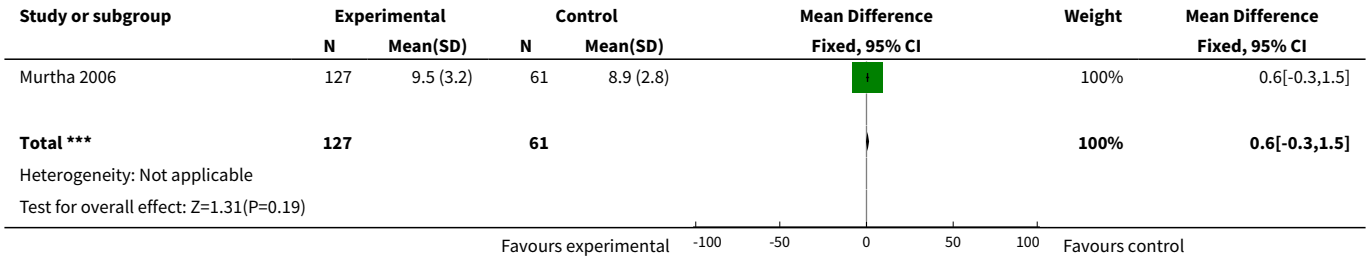
Analysis 4.4. Comparison 4 Barbed suture versus PDS suture, Outcome 4 Seroma.



Analysis 4.5. Comparison 4 Barbed suture versus PDS suture, Outcome 5 Skin separation.



Analysis 4.6. Comparison 4 Barbed suture versus PDS suture, Outcome 6 Time to skin closure of dermal and epidermal layer (minutes).



APPENDICES

Appendix 1. Methods used to assess trials included in previous versions of this review

The following methods were used to assess Frishman 1997.

Two reviewers independently assessed the studies to include. One reviewer has an expertise in obstetrics, the other has a health services research background. Any articles where there was a dispute regarding inclusion were assessed by the third reviewer.

We assessed study quality using the criteria outlined in the Cochrane Handbook (Clarke 2000). In addition to adequate allocation concealment, we also assessed blinding of outcome assessment and loss to follow up. We abstracted data onto 'hard copy' data sheets. We then entered data onto the Review Manager computer software (RevMan 2000), which was checked by two reviewers independently for accuracy, and analysed using RevMan 2000.

Results are presented using relative risk for categorical data and weighted mean difference for variables measured on a continuous scale indicating 95% confidence intervals. As there was only one study, we did not carry out a meta-analysis. However, if further trials are identified in the future, we will pool the results using a fixed effect model, which provides an average measure of treatment effect in the studies being analysed. In the presence of significant heterogeneity between studies the planned subgroup analysis and sensitivity analysis will provide valuable information to interpret findings.

Furthermore, in future work, we will conduct subgroup analyses to explore differences between elective and emergency caesarean sections as emergency sections may have a higher risk of endo-peritoneal infections and subsequent skin infection. We will also conduct subgroup analyses of vertical versus horizontal skin incisions and first caesarean section versus repeat caesarean section. We will explore the influence of trial quality on the findings of the review by conducting a sensitivity analysis of adequate allocation concealment versus unclear allocation concealment as outlined in the Cochrane Handbook (Clarke 2000).

Outcome data that we have not prespecified, but have been reported by the authors, are discussed and are labelled 'not specified' in the analysis. The conclusions of the review are based on prespecified outcomes.

FEEDBACK

Padavala, November 2005

Summary

The author's comment under 'Implications for research' that 'It is also important to explore the ability of the scar to withstand rupture in future pregnancies'. I am sure the review authors agree that skin suturing has no bearing on 'uterine scar rupture' in future pregnancies, and that 'rupture of skin scar' in subsequent pregnancies has never been reported. I hope this sentence is corrected in future updates.

[Summary of comment from Sudha Padavala, November 2005]

Reply

We agree and excluded this sentence from our update.

[Reply submitted by Dhanya Mackeen, February 2012]

Contributors

Sudha Padavala

WHAT'S NEW

Date	Event	Description
15 October 2012	Amended	The Juergens 2011 study was previously excluded because it did not report sufficiently on the outcomes of interest. However, since this study does meet the inclusion criteria for this review, it has now been reclassified as included but does not contribute any data towards the analyses.
15 October 2012	New citation required but conclusions have not changed	The results and conclusions have not changed.

HISTORY

Protocol first published: Issue 2, 2002
Review first published: Issue 2, 2003

Date	Event	Description
10 January 2012	New search has been performed	Search updated. Nine new trials included: Basha 2010; Cromi 2010; Gaertner 2008; Murtha 2006; Myers 2006; Rengerink 2011; Roungsipragarn 2001; Rousseau 2009; Tan 2008.
10 January 2012	New citation required but conclusions have not changed	A new review team updated this review.
1 October 2009	Amended	Search updated. Fourteen reports added to Studies awaiting classification.
12 November 2008	Amended	Converted to new review format.
1 November 2005	Feedback has been incorporated	Feedback incorporated from Sudha Padavala, November 2005
30 May 2004	New search has been performed	New search conducted but no new trial reports identified.

CONTRIBUTIONS OF AUTHORS

Dhanya Mackeen (DM), Vincenzo Berghella (VB) and Mie-Louise Larsen (ML) updated the protocol and the review. DM and ML assessed papers for inclusion. DM and ML abstracted the data. VB and DM completed the Characteristics of included studies tables. ML and DM completed the risk of bias tables. DM wrote the first draft and entered the data. All authors assessed the data entry for correctness.

DECLARATIONS OF INTEREST

None known.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None.

NOTES

None.

INDEX TERMS

Medical Subject Headings (MeSH)

*Abdominal Wound Closure Techniques; *Dermatologic Surgical Procedures; *Suture Techniques; *Sutures [adverse effects]; Cesarean Section [*methods]; Randomized Controlled Trials as Topic; Surgical Wound Dehiscence [etiology]; Surgical Wound Infection [etiology]

MeSH check words

Female; Humans; Pregnancy